PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

plicant's or agent's file reference 1229	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
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ernational Patent Classification (IPC) or national classification and IPC t. Cl.[7] C07K 2/00, 7/00, 7/04, 7/06, 7/08, 14/71, 14/715; A61K 38/19, 38/20; A61P 35/00, 43/00		
pplicant MEDVET SCIENCE PTY LTD et al		

This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

This REPORT consists of a total of 5 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, comprising:

a. ☐ *(sent to the applicant and to the International Bureau)* a total of sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 25 May 2005	Date of completion of the report 22 September 2005
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001482

No. I Basis of the report

With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1 (b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☒ the international application as originally filed/furnished

☐ the description:

pages	as originally filed/furnished	
pages*	received by this Authority on	with the letter of
pages*	received by this Authority on	with the letter of

☐ the claims:

pages	as originally filed/furnished	
pages*	as amended (together with any statement) under Article 19	
pages*	received by this Authority on	with the letter of
pages*	received by this Authority on	with the letter of

☐ the drawings:

pages	as originally filed/furnished	
pages*	received by this Authority on	with the letter of
pages*	received by this Authority on	with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Statement		
Novelty (N)	Claims	YES
	Claims 1-79	NO
Inventive step (IS)	Claims	YES
	Claims 1-79	NO
Industrial applicability (IA)	Claims 1-79	YES
	Claims	NO

Citations and explanations (Rule 70.7)

Novelty and Inventive Step

D1 WO 1996/021000
D2 US 5112961 A (HAYASHIDA) 12 May 1992
D3 Palacios, C et al Current Biology, 2001, vol 11 pages 1439-1443
D4 Stomski, F. C et al Blood, 1999, vol 94 no 6 pages 1933-1942
D5 DATABASE NCBI (protein) Accession Number AAA18171
D6 DATABASE NCBI (protein) Accession Number P48357
D7 DATABASE NCBI (protein) Accession Number P40189
D8 Lewis, R. E. et al, The Journal of Biological Chemistry, 1994, vol 269 no 42 pages 26259-26266
D9 Merida, I. et al The Journal of Biological Chemistry, 1993, vol 268 no 9 pages 6765-6770
D10 Paolini, R et al Proceedings of the National Academy of Science USA, 1992, vol 89 pages 10733-10737
D11 Imler, J-L et al, The EMBO Journal, 1992, vol 11 no 6 pages 2047-2053
D12 Ferris, D K et al, Biochemical and Biophysical Research Communications,1988, vol 154 no 3 pages 991-996
D13 Gammeltoft, S et al, Biochem. J, 1986, vol 235 pages 1-11

D1-D13 were cited in the International Search Report.

Claims 1-27 are directed to sequences and are prima facie not novel and not inventive in light of the admitted prior art sequences on page 24 of the description.

D1 discloses an antibody CDR having sequences that include serine/threonine and tyrosine, for example, SYSVH and DPPSSLLRLDY. The latter sequence anticipates claim 4. Therefore serine/threonine and tyrosine occur in the binding region of the antibody and hence would likely be capable of forming part of a binding sequence elsewhere. Many other patents disclose CDRs that include serine/threonine and tyrosine. Therefore claims 1 and 4 are not novel and not inventive in light of D1.

D2 discloses the amino acid sequence of the β chain of GM-CSF. Therefore claims 1-11 and 13-27 are not novel and not inventive in light of D2.

D3 discloses that phosphorylation of threonine and tyrosine residues in the TPY activation loop motif activates JNK. Therefore claims 1, 2, 28 and 31 are not novel and not inventive in light of D3.

x No. VIII Certain observations on the international application

e following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully ported by the description, are made:

Claims 1-1 and their appended claims are not fully supported by the description because they are not limited to the binding motif on the β chain of the receptors for GM-CSF, IL-3 and IL-5 as per the description.

Claims 1-79 are not clear with regard to the scope of the phrase "bidentate motif" and "or equivalent thereof".

Claim 9 is not clear because there are two receptors numbered "(30)".

Claim 35 is not supported by the description with regard to the phrases "Tyr is substituted for Phe and/or the Ser is substituted for Gly".

Claim 73 is not clear because of the phrase "the cytokine indicated condition is carrier".

Claims 1-27 appear to be statements of the discovery and do not define the invention which is in the methods of using the discovery that the binding motif of a receptor capable of binding a cytoplasmic protein must be an amino acid sequence which has serine/threonine and tyrosine residues.

Claims 1-27 are not clear. The said claims define a bidentate motif capable of binding to a cytoplasmic protein. Some of the claims give sequences for the motif. It is considered that any protein, polypeptide or peptide which binds to a cytoplasmic protein via a sequence that contains a serine/threonine and tyrosine and/or possesses the sequences claimed, falls within the scope of the claims.

pplemental Box

ase the space in any of the preceding boxes is not sufficient.

ntinuation of: Box V

suggests that the 14-3-3 binding sequence 582HSRSLP587 with the SHC binding sequence 577Tyr forming a notif perhaps involved in certain specialized functions associated with the GM-CSF, IL-3 and IL-5 receptors". herefore claims 1-79 are not novel and not inventive in light of D4.

discloses the amino acid sequence of the common β chain of the GM-CSF, IL-3 and IL-5 receptors. Given that any otein, polypeptide or peptide with the sequence of GM-CSF is considered to anticipate claims to the bidentate motif e also Box VIII), claims 1-27 are not novel and not inventive in light of D2.

6 discloses the amino acid sequence of the leptin receptor. Therefore claims 1-11 and 13-27 are not novel and not ventive in light of D6.

7 discloses the amino acid sequence of the interleukin-6 receptor. Therefore claims 1-11 and 13-27 are not novel and t inventive in light of D7.

8 discloses in regard to the insulin receptor that the juxtaposition of serine phosphorylation sites with sites of receptor rosine autophosphorylation may play a role in modulating signals from the cytoplasmic domain. Therefore claims 1- , 9, 11, 13, 28, 31-33, 46 and 54 are not novel and not inventive in light of D8.

9 discloses that serine and tyrosine residues on the β chain in IL-2Rβ participate in the interaction with protein rosine kinase. Therefore claims 1-2, 11, 13-15, 19, 28, 31, 46 and 54 are not novel and not inventive in light of D9.

10 discloses that serine and tyrosine residues on the β chain (or threonine and tyrosine on the γ chain) are hosphorylated on engagement of IgE receptor. Dephosphorylation of β and γ chains occurs on disengagement of the eceptor. Therefore although not explicitly stated, this implies that both serine and tyrosine and both threonine and yrosine are involved in a binding motif. Therefore claims 1-2, 9, 13-15, 28-29, 31 and 46 are not novel and not nventive in light of D10.

11 discloses that the three amino acids Ser 132, His 133 and Tyr134 play a critical role in IL-2 binding. Therefore laims 1-11 are not novel and not inventive in light of D11.

12 discloses that P-Ser and P-Tyr increase with administration of IL-3 and co-activation of serine/threonine and yrosine kinase activity may be important in IL-3 signal transduction. Therefore claims 1-79 are not novel and not nventive in light of D12.

D13 discloses that serine/threonine and tyrosine phosphorylation on the β subunit regulates insulin receptor kinase. Therefore claims 1-2, 9, 11, 13-15, 28-29, 31-33, 46, 54, and 57-59 are not novel and not inventive in light of D13.